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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,517	10/16/2003	Amar Lulla	33396-198024	4905

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
11/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,517	LULLA ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,8,10,12,14,15,17-20,23,25,26,31-33,35,37-40,44,45 and 74-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,6,8,10,12,14,15,17-20,23,25,26,31-33,35,37-40,44,45 and 74-83.

DETAILED ACTION

Acknowledgment of Papers Received: Petition Decision dated 8/30/10. Remarks/Amendments date 8/5/10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6, 8, 10, 12, 14, 15, 17-20, 23, 25, 26, 31-33, 35, 37-40, 44, 45, and 74-83 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Osipow et al (USPN 4,328,319 hereafter '319) in view of Biedermann et al (USPN 5,980,921 hereafter '921).

The '319 patent discloses a topical sprayable pharmaceutical comprising 0.02 to about 15% of at least one medicament including (col. 12, lin. 15-38). The medicaments include hormones like hydrocortisone (col. 12, lin. 25) and antibiotics (col. 12, lin. 5-20). The formulation comprises film formers such as acrylic polymers like alkyl acrylate and alkyl

methacrylate copolymers (col. 8, lin. 55-col. 9, lin. 10). These polymers are present in concentrations up to 50 %, and as low as 10.4% (Example 1). The formulation further comprises permeation enhancers such surfactants or oleic acid in a concentration from 0.0001-8% (col. 7, lin. 5-31). The formulation further comprises plasticizers such as tributyl citrate in a concentration from 0.0001-10% (col. 10, lin. 60-col. 11, lin. 11, example 1), propylene glycol as a humectant, and various non-aqueous solvents and vehicles such as trichlorofluoromethane, ethanol acetone and methylene chloride, sodium lauryl sulphate as a solubilizer (col. 8, lin. 15-32, col. 7, lin. 6, 55-69, col. 10, lin. 52-59). The film composition can be sprayed using a propellant such as P114 or P22 present in a concentration from 20-70% (col. 9, lin. 20-67 and col. 10, lin. 3-7). The film is useful in topical applications for soaps, or makeup (col. 11, lin. 35-60). When sprayed or applied the composition forms a porous film material that acts as a carrier for medicament, cleansers or pigments (col. 14, lin. 1-50). This porous foam film meets the "breathable film" limitations of the instant claims as defined in the instant specification. The porous nature of the film would not interfere with the metabolic activities of the skin, thus being "breathable".

The reference differs from the instant claims in the disclosure of the plasticizers. The reference discloses several plasticizers such as tributyl citrate and other citrate esters, yet is silent to the specific plasticizer of claims 74 and 75. The inclusion of this well known plasticizer would be an obvious addition to the formulation as shown by the '921 patent.

The '921 patent teaches a topical composition comprising a an active agents (present in a concentration from 3-5%), film-forming polymer (povidone) and vehicle (water) along with a plasticizer (dimethyl isosorbide) (from 5-20%) (Abstract, col.4, lin. 38-44, col. 5, lin. 20-25,60-

65, col. 9. lin. 29-44, and col. 10, lin. 17-25). The compositions are sprayed onto the skin and are intended to stay put providing a stable film that is water resistant (col. 14, lin. 30-38; examples). The active agents include anti-inflammatory agents such as hydrocortisone (col. 11, lin. 1-46). It would have been obvious to include the plasticizer of the '921 patent in to the formulation of the '319 since the formulation are similar in that they both form thin breathable films.

Regarding the specific concentration of the components of the instant claims it is the position of the Examiner that such limitations do not distinguish over the prior art. The prior art combination discloses a sprayable film comprising a medicament, film forming polymers in a non aqueous carrier. Each component is identical to the instant claims. The film forming polymers are present as low as 10.4%, while the instant claims recite a range of up to about 10%. It is the position of the Examiner that 10.4% is within the range of "about" 10% and would be the obvious result of routine optimization by those of ordinary skill in the art. The prior art provides a sprayable film comprising identical component sin similar if not identical concentrations for the same purpose, within the same field of endeavor. The general conditions of the claim have been met by the prior art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

With these things in mind it would have been obvious to include the plasticizing solvent of the '921 patent into the formulation of the '319 patent in order to reduce tackiness and thus reduce the evenness of the sprayed film. One of ordinary skill in the art would have been motivated to make the simple substitution since the formulation are similar in composition and

purpose, both delivering active agents topically via a sprayed film formulation comprising film forming polymers, vehicles and plasticizers, solvents and propellants. It would have been obvious to combine the teachings in the art with an expected result of a non-tacky drug delivery film that is breathable and stable.

Response to Arguments

Applicant's arguments filed 8/5/10 have been fully considered but they are not persuasive. Applicant argues that: The prior art combination does not disclose a breathable film as recited in the instant claims since the Osipow does not disclose a film product and the Biedermann patent does not remedy the many deficiencies of the Osipow patent.

Regarding the argument that only claims 74 and 75 have been addressed in the 103 rejection, this is not found persuasive since all the claim limitations were addressed in the 10 rejection and obviousness in the epitome of anticipation. Only the specific amount of film-former was lacking with is addressed in the 103 rejection.

Regarding this argument it remains the position of the Examiner that the combination of the Osipow and Biedermann patents continue to obviate the instant claims. The Osipow patent discloses a porous foamed product that forms a film upon spraying, that retains it shape and resists rubbing off (col. 15, lin. 1-5). The film comprises 0.02-15% of a medicament (col. 12, lin. 35-38), about 10% film-forming polymers in a non-aqueous vehicle (col. 8, lin. 55-68). The formulation comprises at least one permeation enhancer, plasticizer and solubilizer, each identical to compounds recited in the instant claims. Each additional component is present within the same ranges of the instant claims. The film differs from the instant claims in the specific plasticizer used. This plasticizer can be found in the Biedermann patent, which discloses

a topical film product similarly comprises a film forming polymer and a medicament. It would have been and obvious substitution since both patent disclose topical film products comprising similar components.

Application argues that the film of the Osipow patent does not disclose a "breathable film" as recited in the claims, yet discloses a foam product. However, according to the instant specification the "“breathable film” is defined by a film that does not interfere with the normal metabolic functions of the skin; this definition does not preclude foamed films. In fact the porous, foamed nature while providing a stable film that resists shape change would allow the skin to "breath" since it is essential non-occlusive and is merely a carrier for active agents (col. 11, lin. 35-col. 12, lin. 38). Further the claims do not recite physical properties of the film, such as thickness, viscosity, etc. Without these physical parameters, any film like product that meets the compositional requirements (medicament, film forming compounds and one additional compound) should meet the limitations of the claim. The film product of the Osipow is a topical spray composition just as the instant claims recite. It is the position of the Examiner that since the Osipow film product discloses the same collection of components combined in a similar fashion (film formers in a non-aqueous vehicle, along with medicaments, propellants and auxiliary agents all in the same proportions, in topical spray product), the patent obviates the instant claims. The inclusion of a specific plasticizer would have been an obvious substitution since both patents provide similar produce within the same field of endeavor solving the same problem. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
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/MICAH-PAUL YOUNG/
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